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| 23505 | 7590 06/15/2004 | | EXAMINER | |
| CONLEY ROSE, P.C. P. O. BOX 3267 | | | WAX, ROBERT A | |
| HOUSTON, TX 77253-3267 | | | ART UNIT | PAPER NUMBER |
| | | | 1653 | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

| | Application No. | Applicant(s) | |
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| | 09/845,570 | JO ET AL. | |
| Office Action Summary | Examiner | Art Unit | |
| | Robert A. Wax | 1653 | |
| The MAILING DATE of this communication a | ppears on the cover sheet | t with the correspondence address | |
| Period for Reply | | | |
| A SHORTENED STATUTORY PERIOD FOR REF THE MAILING DATE OF THIS COMMUNICATION - Extensions of time may be available under the provisions of 37 CFR after SIX (6) MONTHS from the mailing date of this communication. If the period for reply specified above is less than thirty (30) days, a r If NO period for reply is specified above, the maximum statutory peri Failure to reply within the set or extended period for reply will, by sta Any reply received by the Office later than three months after the ma earned patent term adjustment. See 37 CFR 1.704(b). | N. 1.136(a). In no event, however, ma reply within the statutory minimum of od will apply and will expire SIX (6) I | y a reply be timely filed thirty (30) days will be considered timely. MONTHS from the mailing date of this communication. ARANDONED (35 U.S.C. § 133). | |
| Status | | | |
| 1) Responsive to communication(s) filed on 22 2a) This action is FINAL. 2b) This action is application is in condition for allow closed in accordance with the practice under | his action is non-final. wance except for formal r | natters, prosecution as to the merits is C.D. 11, 453 O.G. 213. | |
| Disposition of Claims | | | |
| 4) Claim(s) 2-20,23,24 and 26-34 is/are pendidal of the above claim(s) is/are without 5) Claim(s) 30 is/are allowed. 6) Claim(s) 2-17,19,20,23,24,26-29 and 31-34 7) Claim(s) 18 is/are objected to. 8) Claim(s) are subject to restriction and are subject to by the Examplicant Papers 9) The specification is objected to by the Examplicant may not request that any objection to Replacement drawing sheet(s) including the country of the part of the subject of | drawn from consideration is/are rejected. ad/or election requirement niner. accepted or b) objecte the drawing(s) be held in ab | d to by the Examiner. beyance. See 37 CFR 1.85(a). wing(s) is objected to. See 37 CFR 1.121(d). | |
| Priority under 35 U.S.C. § 119 | | | |
| 12) Acknowledgment is made of a claim for for a) All b) Some * c) None of: 1. Certified copies of the priority docur 2. Certified copies of the priority docur 3. Copies of the certified copies of the application from the International But * See the attached detailed Office action for a | ments have been received ments have been received priority documents have ureau (PCT Rule 17.2(a)) | I. I in Application No been received in this National Stage | |
| Attachment(s) 1) ∑ Notice of References Cited (PTO-892) 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-94 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/S Paper No(s)/Mail Date | 8) Pap | rview Summary (PTO-413) er No(s)/Mail Date ice of Informal Patent Application (PTO-152) er: | |

DETAILED ACTION

Introduction

1. Upon review of the previous Office action Examiner realized that claim 6 had been inadvertently left out of the rejections and no explanation was provided for allowable subject matter. The amendments made to the claims, especially making claims 2-5 depend from 6 have overcome the previous rejections based on Rhee et al. However, the rejection over Suggs et al., which should have been applied to claim 6 in the previous Office action, is maintained. Additionally, Palladino et al. was discovered which raised further issues. The previously implied indication of allowability of claims 10,16,19, 20 and 23 is hereby withdrawn. Examiner apologizes for any inconvenience.

Claim Rejections - 35 USC § 112

- 2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

 The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
- 3. Claims 9, 13, 14 and 31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 9, the term "comprising" should read "comprises"; regarding claims 13 and 14, the term "including" renders the claim indefinite because it is unclear whether the limitations following the term are the only extracellular matrix molecules

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being claimed; regarding claim 31, the recited steps will make PPF, not OPF since poly (propylene glycol) is reacted with fumaryl chloride.

Claim Rejections - 35 USC § 102

- 4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
- 5. Claims 2-7, 10, 16, 19, 20, 23 and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Suggs et al. (5,527,864).

Suggs et al. teach a polymeric network comprising poly (propylene fumarate) copolymerized with poly (ethylene oxide) and crosslinked with an unsaturated linker monomer. They also suggest radical initiators such as acetyl peroxide, which are known to catalyze polymerization of double bounds. These teachings clearly anticipate claims 2-7 and 24. Claims 10, 16, 19, 20 and 23 are considered to be anticipated as well because once the poly (propylene fumarate-co-ethylene oxide) taught by Suggs et al. is formed the resulting polymer would be indistinguishable from polyethylene glycol fumarate also containing polypropylene oxide.

6. Claims 10, 16, 19, 20 and 23 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Palladino et al.

Palladino et al. teach a polyester prepared from fumaric acid and poly (ethylene glycol) crosslinked with N-vinyl pyrrolidone, see column 19, lines 25-27. This must be

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biocompatible because it is intended for use in IP (intraperitoneal?) administration. This clearly anticipates the above claims.

Claim Rejections - 35 USC § 103

7. Claims 26-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Suggs et al.

The teachings of Suggs et al. have been outlined above. In addition they discuss varying the parameters to study the effect on the properties of the copolymer at column 3, line 58 – column 4, line 61. It is considered well within the ordinary level of skill in the art to vary proportions of ingredients to achieve desired properties, hence it would have been obvious to one of ordinary skill in the art at the time the invention was made to vary the proportions of polyethylene glycol and fumaryl chloride to achieve the desired wet to dry swelling ratio.

8. Claims 8, 9, 29 and 31-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Suggs et al. in view of Patel et al.

The teachings of Suggs et al. have been outlined above.

Patel et al. teach solid carriers for improved delivery of active ingredients in pharmaceutical compositions comprising polyoxyethylene-polyoxypropylene block copolymers (see column 25, line 60 – column 27, line 33) and various additives.

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Additives can be, for example, proteins or carbohydrates including cellulose derivatives, starch and chitosan, see column 40, lines 60-63.

It would have been obvious to one of ordinary skill in the art to utilize proteins or carbohydrates as additives to the compositions of Suggs et al. in order to obtain the advantages taught by Patel et al.

9. Claims 11, 13-15 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Palladino et al. in view of Patel et al.

The teachings of the references are outlined above.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize proteins or carbohydrates as additives to the compositions of Palladino et al. in order to obtain the advantages taught by Patel et al.

10. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Palladino et al. in view of Patel et al. and Hubbell 6,596,267.

The teachings of Palladino et al. and Patel et al. are outlined above.

Hubbell et al. teach bioactive species to be used to target adhesion of polyalkylene oxides that include RGD, YIGSR and REDV, see column 6, lines 19-23 and lines 43-60.

It would have been obvious to one of ordinary skill in the art to utilize the bioactive species taught by Hubbell et al. with the polymers of Palladino et al. as modified by Patel et al. for the advantages taught by Hubbell et al.

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Response to Amendment

11. As stated above, the amendment obviated the rejections based on Rhee et al. Furthermore, Examiner appreciates applicant pointing out the teaching in the specification that was said to be missing; the rejection under 35 USC 112, first paragraph is therefore withdrawn. The previous rejections under 35 USC 112, second paragraph were also obviated. In view of the failure to reject claim 6 and make the above rejections under 35 USC 112, second paragraph, this Office action is nonfinal.

Allowable Subject Matter

12. Claim 18 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The references of record do not teach use of polyethylene glycol to crosslink poly (ethylene glycol) fumarate.

Conclusion

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The *Biomacromolecules* article seems germane to the instant application even though it is not prior art.

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14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A. Wax whose telephone number is (571) 272-0623. The examiner can normally be reached on Monday through Friday, between 9:00 AM and 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher S. F. Low can be reached on (571) 272-0951. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Robert A. Wax Primary Examiner Art Unit 1653